

OUR EXPERIENCE. **YOUR SUCCESS.**

Greenleaf Health is a leading FDA regulatory consulting firm guiding companies through the changing FDA landscape.



ABOUT GREENLEAF HEALTH

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250+ YEARS
OF COMBINED FDA EXPERIENCE



WHY GREENLEAF

Founded in 2007, Greenleaf Health is a leading FDA regulatory consulting firm that provides strategic and technical guidance to pharmaceutical, biotechnology, and medical device companies researching, developing, and manufacturing innovative solutions to pressing global public health challenges.

With decades of experience in senior positions at the FDA and throughout industry, Greenleaf's team of respected professionals brings unmatched expertise that companies need when navigating today's evolving FDA regulatory environment.

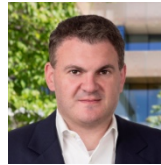
UNMATCHED REGULATORY EXPERIENCE

Greenleaf's robust blend of technical skill and FDA institutional knowledge enables the firm to provide reliable, objective guidance to companies developing medical products for the U.S. market.

Greenleaf experts draw on a combined total of more than 250 years of FDA experience and a network of technical specialists. This wealth of experience informs Greenleaf's understanding of the broad life sciences industry and allows us to deliver valuable insight throughout the product lifecycle.

GREENLEAF HEALTH LEADERSHIP

Greenleaf's team of experts includes former leaders and regulatory professionals from the FDA, Capitol Hill, top global pharmaceutical and medical device companies, leading law firms, and the top U.S. biotechnology trade organization.



**PATRICK
RONAN**

Chief Executive Officer



**JOHN
TAYLOR**

**President
Principal, Compliance &
Regulatory Affairs**



**KATHLEEN
SONNTAG**

Chief Operating Officer



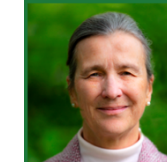
**JOHN
JENKINS, M.D.**

**Principal, Drug &
Biological Products**



**BOB
MEYER, M.D.**

**Principal, Drug &
Biological Products**



**KAREN
MIDTHUN, M.D.**

**Principal, Drug &
Biological Products**



**DANIEL
SCHULTZ, M.D.**

**Principal, Medical Device &
Combination Products**



**MAURA
NORDEN**

**General Counsel
Senior Vice President,
Medical Device &
Combination Products**



**TARYN
WALPOLE**

**Chief of Staff
Executive Vice President,
Regulatory Affairs**

A black and white photograph of five people (three men and two women) sitting around a large conference table in a modern office setting. They are all smiling and looking towards the right. A large green semi-transparent banner is overlaid across the middle of the image, containing the text "GREENLEAF TEAM" in white capital letters. In the foreground, a wooden table with papers and a glass of water is visible.

GREENLEAF TEAM

COMPREHENSIVE SERVICES



PRODUCT QUALITY, MANUFACTURING & COMPLIANCE

Greenleaf experts identify and promote practices and procedures that will align a client's approach with the FDA's quality, safety, and compliance expectations.



DRUG & BIOLOGICAL PRODUCTS

Greenleaf serves as a trusted regulatory partner, advising companies on the complex process of bringing new therapeutics to market and guiding them through product lifecycle management decisions.



MEDICAL DEVICE & COMBINATION PRODUCTS

Greenleaf applies extensive regulatory expertise to guide medical device clients from early-stage development to marketing authorization and throughout the product lifecycle.



REAL-WORLD EVIDENCE (RWE)

Greenleaf Health and Trio Health have united to provide a cutting-edge combination of technology and regulatory insight via Trio's groundbreaking real-world evidence technology platform.



CELL & GENE THERAPY

Greenleaf assists sponsors of cell and gene therapies by optimizing FDA interactions and submissions to support development, manufacturing, quality, and regulatory review.



ADVISORY SERVICES

Greenleaf understands the complex environment within which life sciences transactions take place and frequently advises investors to evaluate potential issues and regulatory risks that may be identified during such transactions.



DRUG & BIOLOGICAL PRODUCTS SERVICES

Greenleaf's Drug and Biological Products Team specializes in providing strategic and technical guidance on medical product development, regulatory review, and postmarket requirements. Greenleaf assists clients with all aspects of the FDA regulatory process, including:



PRODUCT LIFECYCLE MANAGEMENT

Greenleaf serves as a trusted regulatory partner, advising companies on the complex process of bringing new therapeutics to market and guiding companies through product lifecycle management decisions.



PREMARKET REVIEW PROCESS

Greenleaf applies extensive regulatory expertise to guide companies through the premarket review process, providing strategic and technical consultation on: scientific and regulatory practices for clinical programs and regulatory submissions; preparation for FDA meetings, including advisory committees; and FDA communications.



MARKETING & PROMOTIONAL PRACTICES

Greenleaf provides pharmaceutical and biotechnology firms with skilled support on labeling requirements, promotional materials, direct-to-consumer advertising review processes, and use of social media. Experts also guide companies in remediation of untitled and warning letters.

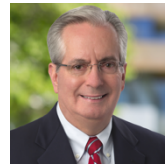


REGULATORY POLICY GUIDANCE

Greenleaf's knowledge and understanding of the FDA enables the firm's experts to offer specialized insight on FDA policies and procedures; user fee requirements; advisory committee decisions and meeting preparation; and implementation of new FDA legislation, regulations, guidance documents, and FDA standard operating procedures.

DRUG & BIOLOGICAL PRODUCTS TEAM

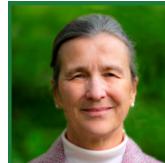
Greenleaf's Drug and Biological Products Team has a robust blend of regulatory and policy expertise and FDA institutional knowledge. The team's approach is guided by decades of regulatory experience in drug and biological product development, spanning all therapeutic areas.



JOHN JENKINS, M.D.
Principal, Drug & Biological Products
Former Director of the Office of New Drugs within the FDA's Center for Drug Evaluation and Research (CDER).



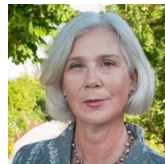
BOB MEYER, M.D.
Principal, Drug & Biological Products
A leader in drug and biological product lifecycle management with over 25 years of regulatory and academic leadership.



KAREN MIDTHUN, M.D.
Principal, Drug & Biological Products
An infectious disease physician by training, with a 28-year career in public service, including as Director of the FDA's Center for Biologics Evaluation and Research (CBER).



JOSEPH GRIFFIN
Executive Vice President, Drug & Biological Products
20+ years of FDA service with a vast institutional knowledge of the drug regulatory process and prescription drug promotion and labeling.



KATE COOK
Executive Vice President, Drug & Biological Products
Two decades of experience in policy development and as legal counsel on biological, medical device, and drug issues.



STEPHEN MASON
Senior Vice President, Regulatory Policy
Accomplished and diverse career specializing in regulatory and legislative policy development and analysis.



BRIAN CORRIGAN
Senior Vice President, Regulatory Policy
More than a decade of experience in the biopharmaceutical industry provides in-depth understanding of the U.S. health care system.



KATIE MCCARTHY
Senior Vice President, Regulatory Policy
10+ years of policy experience specializing in scientific and regulatory issues impacting drug and biotechnology companies.

CELL & GENE THERAPY SERVICES



Greenleaf's cell and gene therapy services support companies striving to introduce new products to patients. The firm's team of experts has a robust blend of technical skill and FDA institutional knowledge that spans all therapeutic areas and quality, manufacturing, and compliance systems. By working cross-functionally, Greenleaf ensures that clients have the comprehensive, specialized guidance needed to understand and navigate the complex regulatory landscape for cell and gene therapies.



PRODUCT DEVELOPMENT & REVIEW

Greenleaf's team specializes in strategic communications with the FDA at every stage of product development – early INTERACT meetings, pre-IND and meetings throughout development, correspondence, clinical trial design, submissions, FDA review communications and labeling discussions, and postmarket requirements.



MANUFACTURING & QUALITY CONTROLS

Greenleaf experts provide strategic and technical support for establishing manufacturing and quality controls; pre- and postapproval inspection readiness; compliance assessments; evaluating and responding to FDA regulatory correspondence; and engaging with CBER's Advanced Technologies Team.

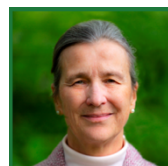


REGULATORY LANDSCAPE

Greenleaf experts monitor and analyze the regulatory environment for emerging trends in cell and gene therapy regulation – including orphan drug designation and exclusivity, long-term follow-up requirements, companion diagnostics, the development and use of real-world evidence, and other agency policies and actions that could potentially impact current development programs – as well as changes to the competitive landscape for cell and gene therapies.

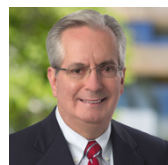
CELL & GENE THERAPY TEAM

Experts from Greenleaf's Cell and Gene Therapy Team demonstrate unmatched levels of skill in their specialties of drug and biological products and product quality, manufacturing, and compliance. Led by Karen Midthun, M.D., and John Taylor, the team is guided by decades of regulatory experience in senior FDA positions, global public health organizations, academia, and industry.



KAREN MIDTHUN, M.D.
Principal, Drug & Biological Products

An infectious disease physician by training, with a 28-year career in public service, including as Director of the FDA's Center for Biologics.



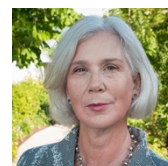
JOHN JENKINS, M.D.
Principal, Drug & Biological Products

Former Director of the Office of New Drugs within the FDA's Center for Drugs.



BOB MEYER, M.D.
Principal, Drug & Biological Products

A leader in drug and biological product lifecycle management with over 25 years of regulatory and academic leadership.



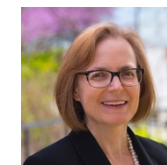
KATE COOK
**Executive Vice President,
Drug & Biological Products**

Two decades of experience in policy development and as legal counsel on biological, medical device, and drug issues.



JOHN TAYLOR
President
Principal, Compliance & Regulatory Affairs

Former FDA senior official held many high-profile positions at the Agency, as well as senior leadership roles within industry.



CYNTHIA SCHNEDAR
**Executive Vice President,
Regulatory Compliance**

25-year compliance career, including serving as director of the FDA's drug compliance office.



KALAH AUCHINCLOSS
**Senior Vice President,
Regulatory Compliance**

10+ years of experience on Capitol Hill, in the private sector, and at the FDA, including role as Deputy Chief of Staff.



DAVID ELDER
**Executive Vice President,
Regulatory Compliance**

23-year veteran of the FDA with prominent roles in domestic and foreign inspections, recalls and emergencies, and compliance actions.



REAL-WORLD EVIDENCE

Real-world evidence (RWE) - the concept of using real-world data (RWD) to improve clinical evidence - has the potential to transform the drug development landscape.

The Food and Drug Administration recognizes the opportunities presented by RWE and has taken steps to develop a new paradigm for its use in regulatory decision-making.

Companies prepared to employ the power of RWE will require more than just raw data -- that's why Greenleaf has partnered with Trio Health to provide a cutting-edge combination of technology and regulatory insight.



GREENLEAF + TRIO

Greenleaf's exclusive agreement with Trio Health, a leading provider of real-time data on real-world patients, gives clients the advantage of Trio's groundbreaking Multi-Disease Platform (MDX) technology integrated with Greenleaf's unrivaled regulatory knowledge. The result is a comprehensive resource for enhancing and contextualizing evidence derived from RWD.



MDX PLATFORM

The first-of-its-kind MDX platform tracks patients throughout the course of their treatment by combining disparate information from the physician, pharmacy, and payer 'trio.' MDX offers life science customers best-in-class speed, data certainty, and unparalleled visibility across the clinical and commercial lifecycle.

Trio's comprehensive and high-quality databases are on caliber with FDA-level rigor, giving pharmaceutical and biotechnology companies, specialty pharmacies, and physicians access to information and opportunities that can be leveraged to support pre- and postmarketing activities.



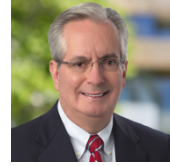
UNRIVALED INSIGHT

When integrated with Greenleaf's regulatory expertise, Trio's advanced analytics MDX platform delivers unrivaled insights to the industry. In particular, clients gain the ability to transform real-world data into actionable intelligence to innovate and make better decisions, with greater confidence, throughout the product lifecycle. Greenleaf's team of regulatory experts provides end-to-end guidance to companies utilizing MDX data on how to optimize and validate the information to drive effective regulatory strategies.

RWE TEAM

Greenleaf's team of regulatory experts provides unmatched insight and consultation on all aspects of the FDA's regulatory application of RWE.

The combined achievements and substantial qualifications of the full Greenleaf team enable a cross-functional, full-service engagement that ensures clients can count on expert direction as they encounter complex regulatory challenges.



JOHN JENKINS, M.D.

Principal, Drug & Biological Products

A 25-year career at the FDA, with 15 years in senior leadership positions within the Center for Drug Evaluation and Research, including as Director of the Office of New Drugs.



BOB MEYER, M.D.

Principal, Drug & Biological Products

More than 25 years of regulatory, industry, and academic leadership, including prominent roles at the FDA, Merck, and the University of Virginia.



KAREN MIDTHUN, M.D.

Principal, Drug & Biological Products

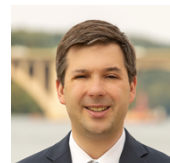
An infectious disease physician by training, with a 28-year career in public service, including as Director of the FDA's Center for Biologics Evaluation and Research.



PATRICK RONAN

Chief Executive Officer

20+ years of leadership experience that includes positions on Capitol Hill, at a leading global pharmaceutical company, and at the FDA, serving as a principal advisor to a number of FDA commissioners.



SEAN HILSCHER

**Associate Vice President,
Regulatory Affairs**

More than 10 years of experience as a consultant and product manager in the international and U.S. health care markets.

ADVISORY SERVICES

Greenleaf's in-depth knowledge and understanding of the FDA equips clients with a trusted partner when considering life sciences transactions.

Greenleaf understands the complex environment within which life sciences transactions take place. This is why the firm considers multiple aspects of a business when performing advisory services, including product development, compliance, enforcement, manufacturing, and regulatory submissions.

By working cross-functionally across our areas of expertise, the Greenleaf team is able to set appropriate expectations for investors and offer insights on the FDA's current thinking in multiple areas. Greenleaf experts work together to provide guidance in the following arenas:



DRUG & BIOLOGICAL PRODUCTS



PRODUCT QUALITY,
MANUFACTURING & COMPLIANCE



MEDICAL DEVICE &
COMBINATION PRODUCTS



CELL & GENE THERAPY



FDA-REGULATED
CONSUMER PRODUCTS

OUR EXPERIENCE.
YOUR SUCCESS.

